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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,763	03/23/2001	Jose Remacle	VANM212.001AUS	4780

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EXAMINER	
CHAKRABARTI, ARUN K	

ART UNIT	PAPER NUMBER
1634	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/816,763	Remacle
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 11, 2002 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-22, 34, and 35 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-22, 34, and 35 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election of claims 1-22, 34, and 35, without traverse, is hereby acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-22, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 10, 18, and 22, the phrase "able to bind" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding claim 12 the phrase "able to interact" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding claim 6, the phrase "possibly" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding claims 8 and 11, the phrase "preferably" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim 3 is rejected over the recitation of the number "6, 8 nm". It is not clear if 6 nm is claimed or 8 nm is claimed or 6-8 nm is claimed or 6.8 nm is claimed or all of them claimed. The metes and bounds of the claim is vague. Proper correction is suggested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8, 11-15, 17-22, and 34-35 are rejected under 35 U.S.C. 102 (b) as being anticipated by Peterson et al. (PCT International Publication NO: WO 95/30026) (November 9, 1995).

Peterson et al teach a screening and/or quantification method of one or more transcriptional factor(s) present in a cell or cell lysate (Abstract), the method comprising the steps of:

a. binding to an insoluble solid support, double-stranded DNA sequences(s) at the concentration of at least 0.01 pmole/square cm of the double-stranded DNA sequence comprising a specific sequence able to bind the transcriptional factor (Abstract, Claim 1, and Examples, Page 16, line 20 to page 17, line 10);

b. putting into contact the transcriptional factor with the bound double-stranded DNA sequence(s) (Examples, Page 17, lines 11-14);

c. Identifying and/or quantifying a signal resulting from the binding of the transcriptional factor(s) upon the double-stranded DNA sequences (Abstract, Claim 1, and Examples, page 17, lines 16-22).

Peterson et al teach a method, wherein the transcriptional factor is present in solution at concentration lower than 20 nM (Examples, Page 17, lines 31-33).

Peterson et al inherently teach a method, wherein the specific sequence of the double-stranded DNA sequence(s) able to bind with the transcriptional factor is located at a distance of at least about 6-8 nm from the surface of the solid support (This inherence is deduced from the fact that Peterson's method uses a coating on the assay plate with N-avidin, and blocks with blocking buffer, and then uses 40 microliter assay buffer. This volume of buffer inherently makes a space of 6-8 nm from the surface of the plate).

Peterson et al teach a method for the possibly simultaneous screening and/or quantification of the multiple different transcriptional factors present in a same biological sample upon the same multiwell plate (Claims 3-7, and page 12, line 16 to page 13, line 27).

Peterson et al teach a method, wherein the signal is a non radioactive resulting signal obtained through an enzymatic reaction (page 9, lines 22-24).

Peterson et al teach a screening and/or quantification method of transcriptional factor selected from AP-1 (Page 12, lines 23-24).

Peterson et al teach a screening and/or quantification method, wherein the spacer is a double-stranded DNA nucleotide sequence of at least 20 base pairs, preferably at least 40 base pairs (Examples).

Peterson et al teach a screening and/or quantification method, wherein the double-stranded DNA sequence(s) are bound to a first member of a binding pair able to interact with a second member of the binding pair bound to the surface of the solid support (Abstract and Examples).

Peterson et al teach a screening and/or quantification method, wherein the double-stranded DNA sequence(s) are covalently bound to the surface of the insoluble solid support (page 11, lines 10-18).

Peterson et al teach a screening and/or quantification method, wherein the consensus sequence is repeated on the same molecule (Column 10, Table 2).

Peterson et al teach a screening and/or quantification method, wherein the double-stranded DNA sequence(s) fixed on the support surface contain in part or totally one or several of the consensus DNA sequences presented in the table 1 (TABLE 1, pages 4-8).

Peterson et al teach a method, comprising the step of identification of at least one characteristic specific of the transcriptional factor activation (Abstract, and Claim 1 and Examples).

Peterson et al teach a method, comprising the steps of screening, quantifying, and/or recovering compounds able to bind to the transcriptional factors or inhibit the binding , when they are put in contact with cells, tissues or organisms (Abstract, and Claim 1 and Examples and page 12, lines 5-30).

Peterson et al teach a method, comprising the steps of screening, quantifying, and/or recovering compounds which modulate the activity of proteins acting on transcriptional factors

and then assayed for the binding to and activity of the transcriptional factors (Abstract, and Claim 1 and Examples and page 12, lines 5-30)

Peterson et al teach a method, which comprises the step of identification of transcriptional factors and peptides which are part of their active complex (Abstract and Claim 1).

Peterson et al teach a method, which comprises the step of adding in the cell lysate an externally added transcriptional factor or a compound which is able to bind to the consensus sequence (page 12, lines 5-30).

Peterson et al teach a method, wherein the first member of the binding pair is biotin and the second member is streptavidin (Examples).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 6-15, 17-22, and 34-35 are rejected under 35 U.S.C. 103 (a) over Peterson et al. (PCT International Publication NO: WO 95/30026) (November 9, 1995).

Peterson et al teach method of claims 1-3, 6-8, 11-15, 17-22, and 34-35 as described above.

Peterson et al teach method of rapid, high-throughput screening (Page 13, lines 10-13).

Peterson et al do not teach the method, wherein the solid support is an array bearing upon at least 4 spots/square cm of solid support surface and a spacer of at least about 13.5 nm.

However, it is *prima facie* obvious that selection of the specific number of spots/square cm in an array and a spacer of specific length represent routine optimization with regard to sequence, length and compositions of the DNA sequences, size of the transcriptional factor being screened and the requirement of screening speed which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of the specific number of spots/square cm in an array and a spacer of specific length performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

8. Claims 1-3, 6-22, and 34-35 are rejected under 35 U.S.C. 103 (a) over Peterson et al. (PCT International Publication NO: WO 95/30026) (November 9, 1995) in view of Voytas et al. (U.S. Patent 5,976,795) (November 2, 1999).

Peterson et al teach method of claims 1-3, 6-15, 17-22, and 34-35 as described above.

Peterson et al do not teach the method, wherein the transcriptional factor is the HIV integrase.

Voytas et al. teach the method, wherein the transcriptional factor is the HIV integrase (Column 2, lines 1-12).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein the transcriptional factor is the HIV integrase of Voytas et al. in the method of Peterson et al , since Voytas et al. state, "The HIV integrase/Ini 1 interaction suggests that retro elements may, in general, recognize specific DNA-bound protein complexes to choose their integration sites (Column 2, lines 9-11)." By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method, wherein the transcriptional factor is the HIV integrase of Voytas et al. in the method of Peterson et al., in order to improve the process for Screening transcription factors and also in order to achieve the express advantages, as noted by Voytas et al., of an invention which provides retro elements that may, in general, recognize specific DNA-bound protein complexes to choose their integration sites.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

March 1, 2002

ARUN K. CHAKRABARTI
PATENT EXAMINER